Trials

REVIEW

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A compound analysis of medical device clinical trials registered in Africa on clinicaltrials.gov

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Abstract

Background Africa, specifically the Sub-Saharan region, has had numerous medical technology clinical trials to address the various healthcare challenges around infectious diseases, non-communicable diseases, and nutritional disorders it is facing. Medical device clinical trials provide performance data in terms of safety, efficacy, and efficiency, which is a requirement before commercialization. Key players such as academicians, governments, international organizations, and funders collaborate to drive these trials, but their growth in Africa remains slower compared to other parts of the globe. This paper aims to evaluate the number of medical device clinical trials conducted in different African countries that are registered on the clinicaltrials.gov website.

Methods Data on medical device clinical trials was mined from clinicaltrials.gov website accessed on 22nd September, 2022. The data extracted was analyzed and cleaned in Microsoft Excel and R. Countries were grouped into regions and descriptive statistical analyses for each region were done. Additionally, frequency distributions were also generated and no inferential statistical tests were performed, as the primary focus of this analysis was to describe the distribution of medical conditions across regions.

Results Thirty-one African countries had registered medical device clinical trials on the website with the majority taking place in Egypt and South Africa. Medical device trials for heart related issues took longer to complete compared to other conditions. Malaria, HIV, and male circumcision related device trials were mainly conducted in Eastern and Southern Africa while trials related to dental, fertility, and obesity were concentrated in Northern Africa. Female reproductive health issues were studied equally across all regions. Some African countries did not have any trials registered on clinicaltrials.gov website.

Conclusion Findings from this study clearly show the disparity in the number, status, and duration of medical device clinical trials across various African countries.

Keywords Medical devices, Clinical trials, Medical innovations, Medical device regulations, Investigational medical devices, Health technology assessment

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Introduction

Numerous medical technology clinical trials have taken place in Africa to address the triple burden of infectious diseases, non-communicable diseases (NCDs), and nutritional disorders it is facing [1, 2]. Though traditional communicable diseases such as HIV, tuberculosis (TB), and malaria have long been the most prominent contributors to the disease burden, Sub-Saharan Africa has witnessed an epidemiological transition to non-communicable diseases (NCDs) in the last two decades [3]. With this, various approaches have been deployed to address these challenges and among them are medical device innovations and their clinical trials. Clinical trials allow for the approval of new innovations, which is one way to improve healthcare outcomes in a sector already strained in many ways. More than 2.74 million clinical trial (CT) studies have been conducted globally, with less than a quarter of them taking place in Africa, according to a review by Taylor-Robinson et al. [4] and yet these trials are a cornerstone of medical research. A clinical trial is the most used method for testing the effectiveness of new medical technology.

The importance of clinical trials is not just limited to what they can yield in terms of scientific knowledge; they also play an important role in providing access to customized healthcare for those who need it most. They are conducted to test the safety and efficacy of new medical products, devices, and procedures [5]. They are essential to monitoring the effectiveness of existing medical technologies, monitoring side effects, and identifying any adverse reactions that may occur during clinical use. This ensures that individuals have access to safe devices that are scientifically proven to be safe and effective. However, without access to clinical trials, many patients in Africa may not benefit from new treatments and medical devices [6].

Although it is logical to run medical clinical trials in Africa because of the diverse population offering potential patients and the many diseases, particularly the neglected and tropical diseases that are endemic, there are a limited number of clinical trials registered and approved to be conducted on the African populations. For example, the non-pneumatic anti-shock garment (NASG) first aid device that was developed to address postpartum hemorrhage and trialed in Zimbabwe in 2013 and Zambia in 2015 [7], the ShangRing device for circumcision [8], the CRADLE vital signs device [9], UniCirc [10], and the urine-based Xpert MTB/RIF for HIV/TB [11] have been tested in Africa and are already in use.

Despite these facts, only 20–30% of global clinical trials are conducted in LMICs and less than 10% in Sub-Saharan Africa [12]. The barriers to conducting clinical trials in Africa include financial and human capacity, delays in regulatory and ethical reviews, complex logistical and financial systems, and competing demands [13]. With this evidence, it is imperative to understand and support medical device trials on the continent. Furthermore, advancing health infrastructure for medical device development will improve access and strengthen the fragile health systems to achieve the universal health coverage (UHC) in Africa. The aim of this paper therefore is to evaluate medical device clinical trials registered on clinicaltrials.gov website in addressing various healthcare challenges in Africa.

Methods

Medical device clinical trial data was extracted from the clinicaltrials.gov website, which is managed by the US National Library of Medicine at the National Institutes of Health and serves as the largest global database for clinical trials. The search focused on African countries using the "devices" term in the "Other terms" field and selecting each country from the dropdown menu. The collected data was then downloaded in comma separated values format, with all suggested columns included.

Subsequently, this data was transformed and loaded into Microsoft Excel. Extraneous information such as enrollment, study result, URL, location, acronyms, study documents, and rank were removed. Start and completion dates were truncated to retain only years after which further cleaning involved focusing solely on interventional studies by excluding observational and expanded access studies. Additionally, excluded were studies not utilizing devices as interventions—specifically those involving only drugs or other non-device related interventions like procedures or behavioral methodologies.

Data analysis

Preliminary data analysis was done using Microsoft Excel 2016 (version 2207). Pivot tables were used to extract tables for the different columns and for this paper we only analyzed the countries, status, start and completion years, primary purpose, funded bys, and conditions. The exact count in the first columns was also calculated and the percentages too were computed. The columns that had ambiguous information such as the conditions column were isolated using pivot tables and exported to R for further analysis. Tables, graphs, and heat maps were drawn using Microsoft Excel 2016 and R and these were used to summarize the number of clinical trials registered per region and per country.

Statistical analysis

The data organized in an Excel worksheet was imported into R (version 4.2.2) for visualization and transformation.

To simplify the visualizations, countries were grouped into regions. This was then followed with various exploratory data analyses using the tidyverse, readxl, maptools, cartogram, coin, and arsenal packages. Clinical trials were grouped by country to generate a count for the total number of trials per country.

Descriptive statistical analyses were conducted to explore the distribution and variability of different medical conditions across the regions, which included Central, Eastern, Northern, Southern, and Western. This involved calculating the mean and standard deviation for each region to quantify the central tendency and dispersion of condition counts. Additionally, frequency distributions were generated to detail the specific counts of each condition within each region. No inferential statistical tests were performed, as the primary focus of this analysis was to describe the distribution of medical conditions across regions.

The status of trials was assessed according to the regions to determine the number of active trials, terminated, suspended, and other categories. This was followed by an analysis of the number of trials funded per country and region, and grouping this according to the funding bodies. Funders were grouped into 3 classes: the National Institutes of Health (NIH), industry, and others which included a combination of any two or three of the other classes. The final analysis was on the primary purpose of the devices under investigation for each of the conditions.

Selection and general characteristics of studies

In the final analysis, only 1170 medical device clinical trial studies were included. A total of 598 studies were excluded, including observational studies ($n=339$), expanded access studies ($n=1$), drug studies ($n=143$), procedure studies ($n=35$), and other interventional studies not focusing on medical devices ($n=50$) as shown in Fig. 1.

Results

Only 31 out of the 54 African countries had recorded medical device clinical trials on clinicaltrials.gov. Northern Africa had the highest number of registered MDCTs, with Egypt contributing to the majority at 795 out of 826. However, the other three Northern African countries, Tunisia, Sudan, and Morocco combined, only accounted for 31 out of these MDCTs. Central Africa had the lowest number of recorded MDCTs at just 8 out of the total of 1170, with only Cameroon, the Democratic Republic of Congo, and Chad having any registered MDCTs. In Southern Africa, South Africa led with 116 out of 168, and in Western Africa, Nigeria was leading with 12 out of 34. Most Eastern African countries had recorded clinical trials, with Uganda leading at 47 out of 134, followed by Kenya and Tanzania at 35 and 23, respectively. Burundi had only one registered MDCT, while Comoros, Somalia, Somaliland, Djibouti, and Eritrea did not have any registered medical device clinical trials. Table 1 and Fig. 2 show the detailed analysis of this dataset.

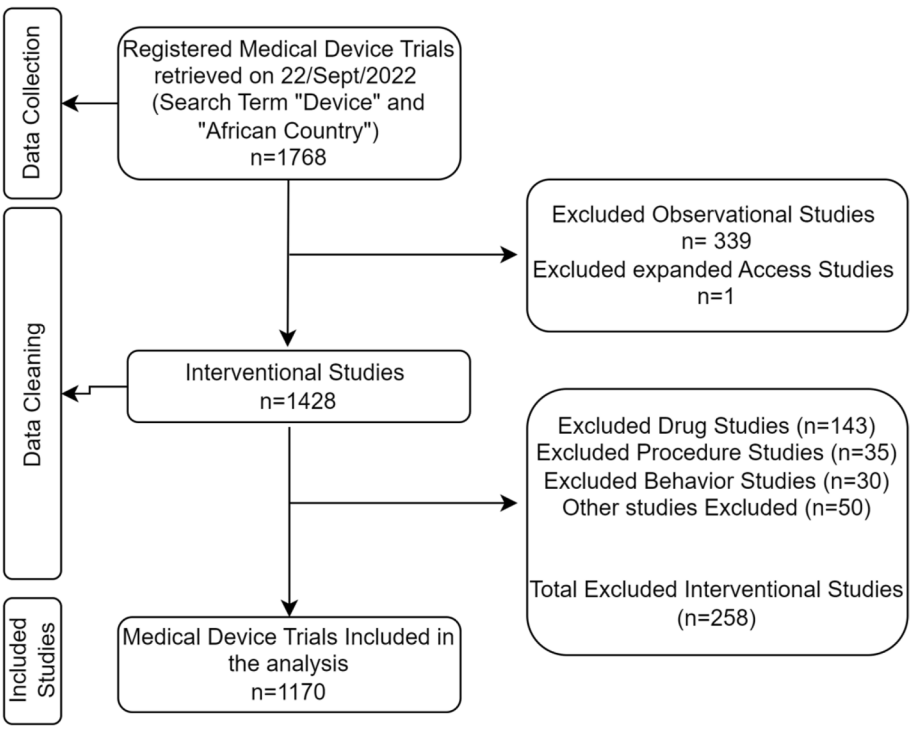

Fig. 1 Flowchart for the selection and data sorting of medical device clinical trials registered on clinicaltrials.gov website considered in this study

Table 1 The number of medical device clinical trials carried out in the various African countries

Country	Number of MDCTs	Percentages
Northern Africa		
Egypt	795	67.95
Tunisia	25	2.14
Sudan	3	0.26
Morocco	3	0.26
Sub Total	**826**	**70.60**
Southern Africa		
South Africa	116	9.91
Zambia	20	1.17
Zimbabwe	11	0.94
Malawi	10	0.85
Mozambique	6	0.51
Botswana	5	0.43
Sub Total	**168**	**14.36**
Eastern Africa		
Uganda	47	4.02
Kenya	35	2.99
Tanzania	23	1.97
Rwanda	16	1.37
Ethiopia	5	0.43
Mauritius	5	0.43
Madagascar	2	0.17
Burundi	1	0.09
Sub Total	**134**	**11.45**
Western Africa		
Nigeria	12	1.03
Gambia	5	0.43
Mali	4	0.34
Burkina Faso	3	0.26
Senegal	3	0.26
Cote D'Ivoire	3	0.26
Liberia	1	0.09
Sierra Leone	1	0.09
Benin	1	0.09
Guinea Bissau	1	0.09
Sub Total	**34**	**2.91**
Central Africa		
Cameroon	5	0.43
DRC	2	0.17
Chad	1	0.09
Sub total	**8**	**0.68**
Grand Total	**1170**	**100**

Health conditions being addressed per region

There were a variety of conditions under investigation across the continent as shown in Fig. 3. These MDCTs were focusing on HIV, malaria, tuberculosis, both male and female reproductive conditions, infectious diseases, non-communicable diseases, rehabilitation, and assistive devices among others. Female reproductive health issues and devices for contraception were studied fairly equally across the Eastern, Northern, and Southern regions while almost all other health issues had regional differences in emphasis. We conducted descriptive statistical analyses to explore the distribution and variability of

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Gambia	5	0.43
Mali	4	0.34
Burkina Faso	3	0.26
Senegal	3	0.26
Cote D'Ivoire	3	0.26
Liberia	1	0.09
Sierra Leone	1	0.09
Benin	1	0.09
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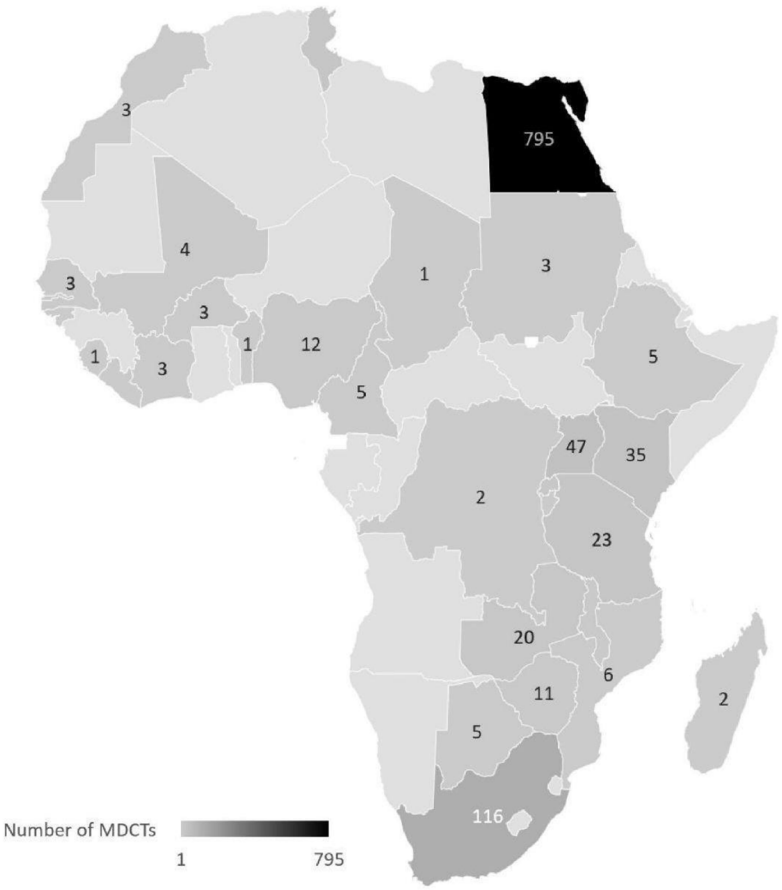


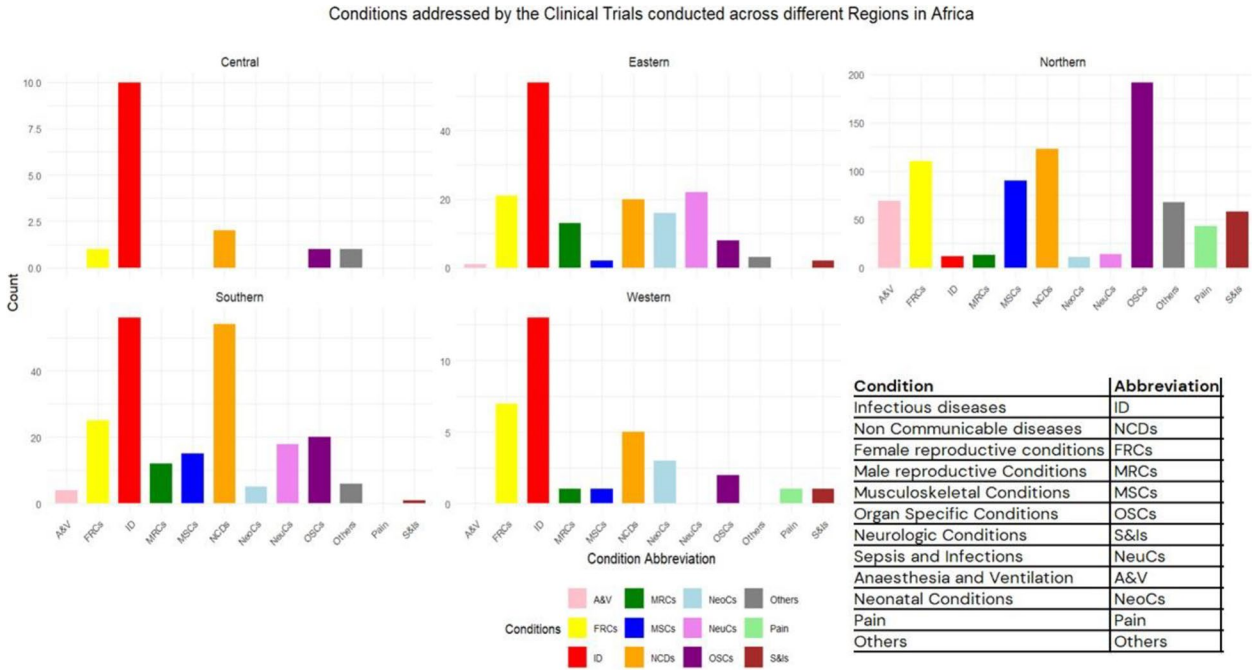
Fig. 2 The number of medical device clinical trials carried out in the various African countries

different medical conditions across five regions: Central, Eastern, Northern, Southern, and Western. The analysis involved calculating the mean and standard deviation for each region to quantify the central tendency and dispersion of condition counts. The Northern region exhibited the highest burden of medical conditions, with a mean count of 66.92 cases per condition and a standard deviation of 55.34, indicating a wide variation in the prevalence of different conditions. The Southern region followed with a mean count of 18.00 and a standard deviation of 18.97, suggesting a moderate level of prevalence and variability. The Eastern region had a mean count of 13.50 and a standard deviation of 15.26, while the Western region showed a lower mean count of 2.83 and a standard deviation of 3.86. The Central region had the lowest mean count of 1.25 and a standard deviation of 2.83, indicating the least burden and variability among the regions.

In the North, most MDCTs were on dental conditions such as cleft palate, dental caries, and pulpitis, male reproductive conditions like erectile dysfunction, and pain management. This region also had more studies on non-communicable diseases, especially diabetes and obesity, and trials on neurodegenerative conditions. MDCTs on prosthetics were only registered in Northern Africa.

Trials on HIV/AIDS, infectious diseases, and circumcision were more concentrated in the Southern and Eastern African countries. Eastern Africa registered more trials on malaria and neonatal health than other regions, while Southern Africa registered more trials on tuberculosis. Most of the trials from Western Africa were on malaria and female reproductive conditions.

All the regions had MDCTs on COVID-19.



Condition	Abbreviation
Infectious diseases	ID
Non Communicable diseases	NCDs
Female reproductive conditions	FRCs
Male reproductive Conditions	MRCs
Musculoskeletal Conditions	MSCs
Organ Specific Conditions	OSCs
Neurologic Conditions	S&Is
Sepsis and Infections	NeuCs
Anaesthesia and Ventilation	A&V
Neonatal Conditions	NeoCs
Pain	Pain
Others	Others

Fig. 3 Faceted graph showing the various healthcare challenges being addressed for the various clinical trials reported in clinicaltrials.gov across the different African regions

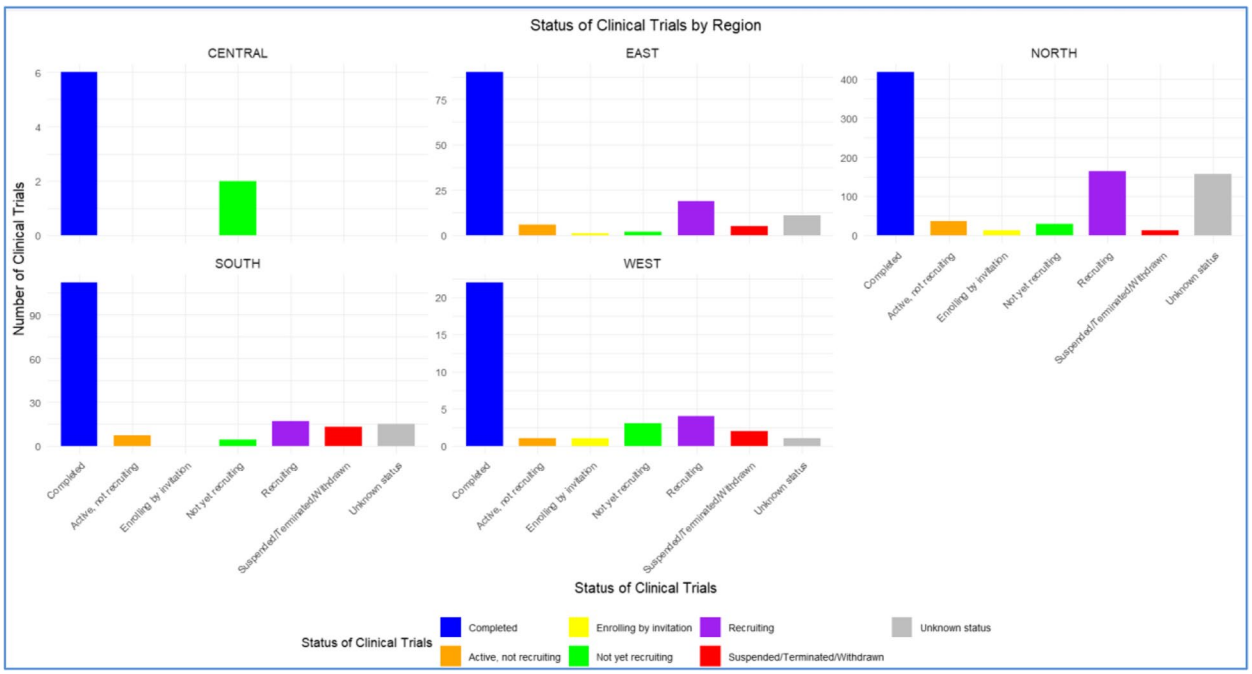


Fig. 4 Faceted bar graph showing the status of medical device clinical trials registered on clinicaltrials.gov across the different African regions

Status by region

Half of all the registered MDCTs ($n=643$, 55.3%) had been completed by the time the site was accessed. Despite having fewer studies than other regions, Western and Central Africa had most of their trials completed compared to other regions. A number of MDCTs ($n=204$) in all regions except Central Africa were recruiting participants. There were MDCTs that were either active but not

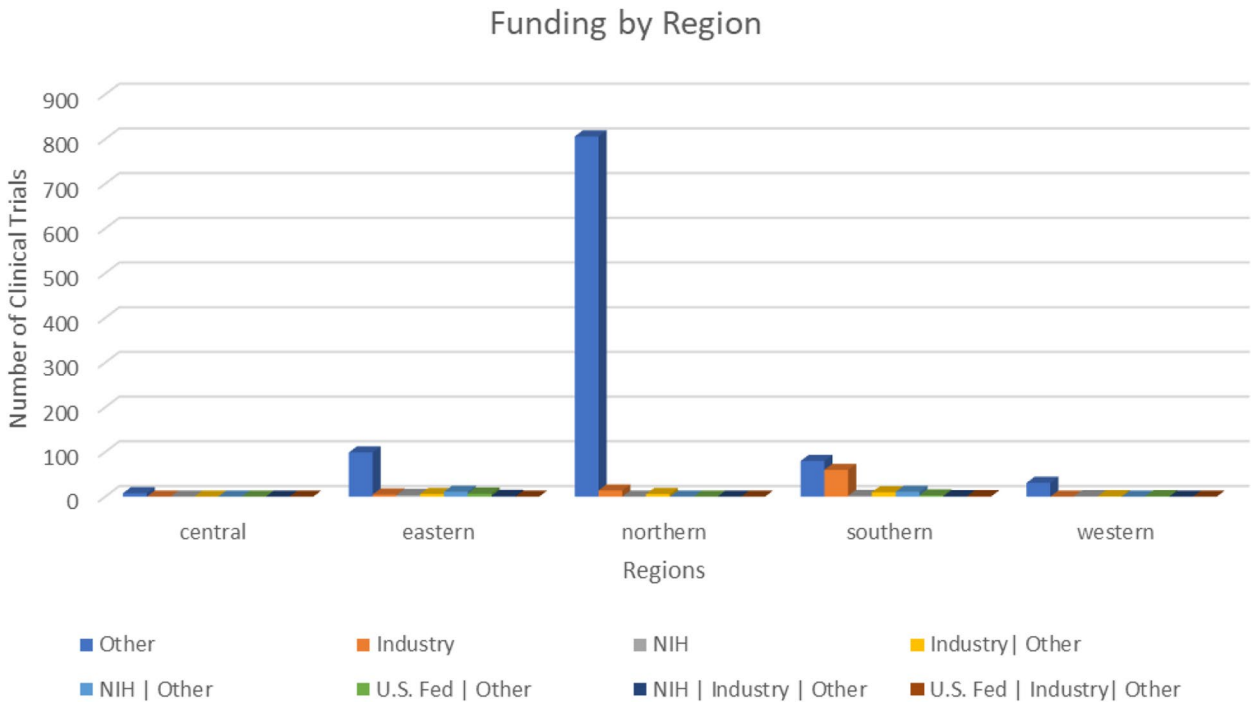


Fig. 5 Funders of medical device clinical trials across the different African regions

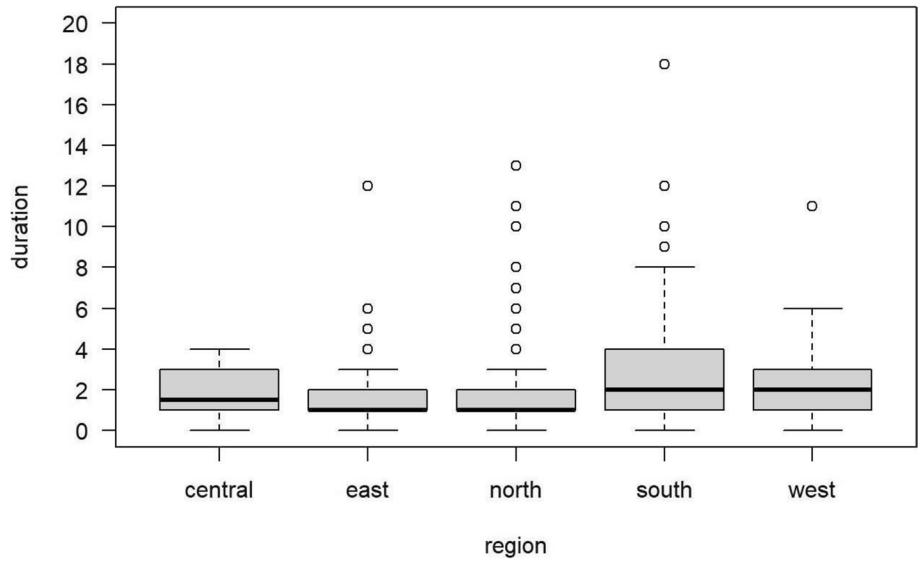


Fig. 6 A box plot showing the duration of medical device clinical trials in the various African regions

recruiting, enrolling by invitation, or not yet recruiting as shown in Fig. 4.

A few studies had been suspended, others terminated, and some were withdrawn. A significant number of studies had an unknown status ($n=183$, 15.6%). All suspended trials were from Northern Africa.

Funding per region

There were four categories of funders recorded on the clinicaltrials.gov website: the US National Institutes of Health (NIH), other US federal agencies, industry, and all others. There was a variety of collaborations among funders to sponsor MDCTs across the African continent as shown in Fig. 5.

Seventy-nine trials were funded exclusively by industry, the majority of which were from Southern ($n=60$) and Northern ($n=14$), and the rest from Eastern Africa ($n=5$). Seven MDCTs were funded exclusively by the NIH with Eastern Africa having the majority of these trials ($n=4$). Other US federal agencies, for example, the Centers for Disease Control and Prevention, collaborated with industry and other funders and were involved in a total of 12 MDCTs.

The majority of medical device clinical trials were funded exclusively by all other bodies ($n=1024$, 87.5%) besides the NIH and US federal agencies. Funding for these MDCTs was through collaborations between universities, hospitals, European institutions like the Medical Research Council (MRC), the European Institute of Oncology, and foundations such as the Bill and Melinda Gates Foundation.

Duration of clinical trials in each region

Duration for MDCTs was obtained as the difference between the start year and completion year as recorded for each trial on the website. Trials whose completion year was beyond 2019 were also labeled as COVID affected. The duration of MDCTs was compared between the different regions as shown in the box plot in Fig. 6.

Southern and Western Africa had a similar median duration of 2 years for MDCTs, which was significantly higher than all other regions. Southern Africa also had the most dispersed distribution which indicated that the duration of MDCTs in this region was much more spread out than other regions. Western and Southern Africa had positively skewed distributions; however, the skew observed in the west was less significant since the median line was in the middle of the box.

Eastern and Northern Africa had a median duration of 1 year. However, this was found close to the lower quartile, which indicates that the mean duration of trials in these regions is greater than the median. Nonetheless, MDCTs in these regions were the least dispersed distribution, with the duration of MDCTs in these regions ranging from 1 to 2 years.

Central Africa had an almost symmetrical distribution despite the negative skew indicated by the median duration closer to the lower quartile. This meant that most of the trials in the region lasted longer than the median duration of approximately 1.5 years. Outliers existed in all regions except Central Africa. Northern Africa had the highest number of outliers, while South Africa had the most significant.

Primary purpose of device under trial per condition

The majority of the devices that were undergoing clinical trials were for treatment purposes ($n=715$) and of these oral ($n=121$) and skeletal health ($n=72$) problems were the majority.

Table 2 The proportion of various purposes for the various medical device clinical trials carried out and the different healthcare conditions they were addressing

Conditions	Basic science	Device feasibility	Diagnostic	Health services research	Others	Prevention	Screening	Supportive care	Treatment
Infectious diseases	0.6	1.9	37.9	5.6	1.2	31.7	3.1	1.2	16.8
Non-communicable diseases	2.5	1.5	10.8	2.0	2.9	13.7	2.5	7.4	56.9
Female reproductive conditions	0.0	0.6	14.6	5.5	6.1	17.1	4.9	4.3	47.0
Male reproductive conditions	0.0	0.0	0.0	5.1	2.6	43.6	0.0	0.0	48.7
Musculoskeletal conditions	0.9	0.0	0.0	1.9	2.8	3.7	1.9	1.9	87.0
Organ-specific conditions	0.4	2.7	3.6	3.6	1.3	5.8	1.3	1.3	79.8
Sepsis and infections	0.0	0.0	8.5	3.4	5.1	54.2	10.2	3.4	15.3
Neurologic conditions	0.0	0.0	3.2	1.6	0.0	3.2	0.0	3.2	88.7
Anesthesia and ventilation	1.4	1.4	13.5	2.7	8.1	10.8	1.4	9.5	51.4
Pain	0.0	0.0	0.0	0.0	2.3	11.4	0.0	9.1	77.3
Neonatal conditions	0.0	0.0	22.9	8.6	0.0	5.7	5.7	11.4	45.7
Others (wounds, burns, and others)	0.0	1.3	5.1	0.0	5.1	14.1	0.0	7.7	66.7

Devices for prevention ($n=201$) and diagnostic ($n=144$) purposes were also in high number. Among the devices for prevention purposes were those addressing HIV ($n=34$), infections ($n=30$), female reproductive issues ($n=19$), and circumcision ($n=16$). Diagnostic devices were mainly addressing conditions such as tuberculosis ($n=21$), HIV, malaria, and female reproductive conditions all registering 13 devices.

Other MDCTs were carried out for devices intended for health services research ($n=42$), supportive care ($n=54$), screening ($n=32$), basic science ($n=9$), and other purposes ($n=39$) as shown in Table 2.

This table presents the proportional distribution of clinical trials across various medical conditions, delineated by their primary purpose. Diagnostic studies constitute the largest segment (37.9%) of trials for infectious diseases, which underscores a significant research focus on identifying these conditions. Conversely, treatment-focused trials predominate the area of non-communicable diseases, accounting for 56.9% of the trials, highlighting a therapeutic orientation in addressing chronic ailments. For conditions specific to female reproductive health, nearly half of the trials (47.0%) are treatment-oriented, whereas preventive studies make up a notable 17.1%, indicating a balanced approach towards managing and averting these conditions. Male reproductive conditions see a similar emphasis on treatment (48.7%) with a substantial portion of trials also dedicated to prevention (43.6%), reflecting a strategic focus on both managing existing conditions and preventing new occurrences. Musculoskeletal conditions are overwhelmingly represented in treatment trials (87.0%), suggesting a clinical response to the impacts of these conditions. Organ-specific trials show a heavy inclination towards treatment (79.8%), potentially due to the critical nature of these diseases. Sepsis and infections are predominantly addressed through prevention (54.2%), which is essential for diseases where early intervention can be life-saving. Neurological conditions have an overwhelming majority of trials in treatment (88.7%), aligning with the urgency of addressing the debilitating effects of these diseases.

Discussion

Distribution of medical device clinical trials across the various African regions

Despite the under-representation in clinical trials research in Africa compared to the rest of the other six continents, the African continent is considered to be a fertile ground for conducting these MDCTs due to its diversity in patient populations [14, 15]. From our results, North Africa, specifically Egypt, has had a great number of MDCTs compared to any other African country. This result is similar in trend with the performance of this country in other wide spectra, including agricultural sciences, computer applications, engineering and technology, physical sciences, medicine, and veterinary sciences [16]. This could be attributed to the huge investment done in terms of education, research infrastructure, and huge funding at disposal for their researchers and scientists [17]. This trend in medical research extends to other similarly developed parts of the continent like South Africa having the highest rankings compared to their counterparts in other regions of Africa.

Over 22 African countries have not had any MDCT registered on the clinicaltrials.gov website. This needs to be investigated as to why there are few of these trials taking place in these countries. However, some could be attributed to inadequate research infrastructure to support the trials like absence of well-established research and ethics committees, lack of national guidelines, few international collaborators to work with academia in these countries, economics, and political insecurity notwithstanding [13, 18]. Despite all that, this disparity should call for interested parties to address the health burdens in these countries which could potentially be addressed by investing in medical device innovations and research. This argument appears to underpin the inclusion of research within the Sustainable Development Goals especially goal 3.B which focuses on health research for LMICs needs, calling for "supporting the development of research and development of vaccines and medicines for health conditions which affect LMICs".

Healthcare challenges being addressed by medical device clinical trials

A lot of evidence is now available showing the differences in the prevalence of various diseases across the African continent [19, 20]. This evidence explains the difference in the number of MDCTs targeting various health conditions in various regions. Egypt has had an increase in prevalence of NCDs and is currently the leading cause of mortality in the country, with NCDs estimated to account for 85% of all deaths [21]. Cardiovascular diseases accounted for the most deaths of all NCDs, followed by cancer, chronic respiratory diseases, and diabetes. This is also in agreement with our results where MDCTs around oral, dental, kidney, cancer, fertility, and prosthesis among others were more in Egypt compared to other African countries.

Sub-Saharan Africa has the highest prevalence of infectious diseases especially tuberculosis, malaria, and HIV/AIDS among others [22]. This prevalence has a correlation with the number of MDCTs which are more in this region compared to the rest of Africa. With the recent COVID-19 pandemic, we see all regions having COVID-19 medical devices being trialed. The same has been

observed for tuberculosis, cancer, hepatitis, pulmonary, and female reproductive issues. Furthermore, as shown in Table 2, we see the majority of the MDCTs were for therapeutic purposes, followed by prevention and diagnostic purposes. Few devices were trialed for basic science purposes which shows a huge gap in the basic science field on the continent. However, due to diagnostic and screening challenges in Africa, more devices need to be innovated and clinically validated to bridge these gaps.

Partnership and funding for medical device clinical trials in Africa

In the past few years, a number of international organizations, including the African Union, World Health Organization (WHO), and the World Bank, have called for political and economic investment in health science research including medical devices in Africa [23]. This led to the term 10/90 gap that was coined to highlight that only 10% of global health research expenditure is devoted to health needs of developing countries, which account for 90% of the population [24]. This is also evident from our results as few MDCTs have taken place in Africa compared with the present disease burden and also compared with other continents like Europe and America. In order to develop context specific products, many governments and other institutions in Africa have established R&D centers. However, data on global sales, patenting, and research and development spending confirms that the dominant source of innovation by far continues to be high-income countries [25], who focus on their own markets. We see that a lot of funding for these MDCTs in Africa is coming from NIH, MRC UK, and other foreign funders who predominantly come from Europe, America, Canada, and the UK. The individual contributions from the industry make it higher than other funders. The industry like pharmaceutical companies play several different roles in the development and use of medical devices as they mainly finance the research required to develop the technologies. While grants from the NIH among others fund most basic research in academic laboratories, it is largely industry that bears the cost of identifying new molecular entities and technologies and testing them in animal models and human subjects. In addition, scientists employed by industry companies play an important role in evaluating the efficacy, safety, and cost-effectiveness of new devices. Academic medical centers may be unable to perform all these tasks on their own.

With that, less local and or regional funding in Africa is available to push the medical devices agenda [26]. Through the growing collaborations and increased set up of institutions of research and academia on the continent, various industry, philanthropists, and other partners have come on board to be part of the MDCTs in Africa. These international partnerships have allowed African researchers and innovators to raise the quality of their R&D and gain support. We see universities, ministries of health, and local research facilities taking and supporting these trials. There are a few medical device development centers in Africa that are geared to this agenda and some examples include the Medical Device Testing and Evaluation Centre (MD-TEC) at the University of Pretoria-South Africa, the Health Devices Lab at the Council for Scientific and Industrial Research (CSIR) in South Africa, the Medical Devices Innovation Institute (MDII) in Kenya, Medical Devices Testing Centre at the University of Ghana, and the Africa Centre for Health Innovation and Product Development (ACHIPD) in Nigeria among others.

Despite efforts of different African governments and partners to set up innovation centers and the increase in innovations across countries, medical device innovations and research is still low and less reported to the global community. Mpaata et al. in 2022 reports about challenges most medical innovators face in Uganda and points out that many of them have never reached the clinical trials stage [27]. Further research and investigations are needed to support these innovators and have their ideas reach the clinical stage. Lastly, the regulatory capacity of medical devices is limited across the continent; several ongoing initiatives aim to improve ethics and regulatory affairs in Africa [28]. This, hopefully, will lead to an improvement in medical device innovations and clinical trials on the continent.

Conclusion

There has been a growing awareness of the importance of building health research systems across the African continent over time. More evidence is still needed to inform policy and health systems performance, develop global collaborations, and build a sustainable human resource that can support these countries in responding to disease burdens, most prevalent and emerging novel epidemic threats such as COVID-19. Intra-African collaboration on medical device innovations and research should be encouraged as evidenced with the formation of the African Biomedical Engineering Consortium which will boost participation of member countries. The disparities shown in MDCTs across the African continent are an indicator that more investment of resources is needed to address the persistent health diseases burden on the continent and the world at large. The regulatory frameworks around medical device development and research are still lacking and their absence limits the development of appropriate medical devices whose research and accessibility has direct consequences on healthcare delivery in Africa. Further analyses are also required among different databases for clinical trials globally to show Africa's position in conducting MDCTs.

Abbreviations

MDCTs	Medical device clinical trials
NCDs	Non-communicable diseases
TB	Tuberculosis
HIV	Human immunodeficiency virus
CT	Clinical trial
NIH	National Institutes of Health
LMICs	Low- and middle-income countries

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Authors' contributions
BM contributed to the design of the study, data collection, and drafting of the manuscript. SK contributed to the design of the study, data collection, and drafting of the manuscript. NK contributed to the design of the study, data collection, and drafting of the manuscript. MT contributed to the data analysis and drafting of the manuscript. CNM contributed to the data analysis and drafting of the manuscript. JM contributed to the data analysis and drafting of the manuscript. BMu contributed to the analysis and interpretation of the results and participated in reviewing the manuscript. RN contributed to the analysis and interpretation of the data and drafting of the manuscript. MW led statistical analysis of the data and contributed to writing the paper. MPYD revised the manuscript. GWJ revised the manuscript. PK revised the manuscript. RTS contributed to the critical analysis of the results and revised the manuscript. All authors reviewed the final version of the paper.

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Availability of data and materials
The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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