GLOBAL SUPPLY CHAIN FOR CLINICAL TRIALS

RE-SHAPING THE CLINICAL SUPPLY CHAIN IN SUB-SAHARAN AFRICA

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INTRODUCTION

A vast and diverse continent, Africa accounts for one-fifth of the world's total landmass and boasts a population that exceeds Europe and North America, combined. However, it also carries the largest burden of global disease with an estimated 25% of all infections concentrated within its borders. Its population is expected to surge towards 2-billion within the next 5 years. The most genetically diverse population in the world, it has a large potential for urbanised and drug-naïve, clinical trial participants. The need for effective medical solutions has never been more urgent.

Africa's rich tapestry of 54 nations presents a unique challenge for clinical trials. Each country possesses its own regulatory landscape, customs processes, and operational intricacies, often interpreted differently at local levels. This complexity, coupled with the multitude of languages spoken across the continent, has traditionally dissuaded sponsors from conducting large-scale trials. Many have opted for a limited approach, focusing on familiar African countries.

Fortunately, the tide has turned, and a wave of initiatives is being implemented that are significantly enhancing the conducting of clinical trials. In this eBook we will explore the action being taken by stakeholders to improve efficiencies along the route. We'll also look at the steps that Oximio is taking to reshape and enhance the clinical supply chain infrastructure, improving quality and expediting the timelines for multinational trials whilst extending the reach of life-saving treatments to greater patient populations.

Harmonising the Regulatory Landscape

AVAREF

The African Vaccine Regulatory Forum (AVAREF) has implemented a Joint Review process to harmonise the regulatory landscape in Africa and improve the turn-around time for regulatory approvals in clinical trials. This process involves the review of clinical trial applications by regulatory authorities from multiple African countries simultaneously, with the aim of reducing duplication of efforts and expediting the approval process.

BENEFITS OF THE JOINT REVIEW PROCESS

- It ensures that regulatory decisions are made based on the same set of standards, leading to greater consistency and harmonization across African countries.

Overall, the Joint Review process implemented by AVAREF is a promising initiative for harmonizing the regulatory landscape in Africa and improving the turn-around time of regulatory approvals in clinical trials.

- It promotes collaboration and information sharing among regulatory authorities, which can help to identify areas of improvement and increase efficiency in the review process.

- It can lead to a reduction in the time and resources required to obtain regulatory approvals, which is particularly important in the context of clinical trials, where delays can have a significant impact on patient health and wellbeing.

AMA

The Africa Medicines Agency (AMA) is the specialised agency of the African Union (AU), established in February 2019 to regulate medical products and promote access to safe, effective, and quality medicines across the African continent. The AMA, based in Addis Ababa, Ethiopia, works closely with other AU agencies, regional economic communities, and national regulatory authorities to strengthen regulatory

systems and ensure that medicines are available and affordable for all African citizens.

The AMA focuses on regulatory harmonisation, capacity building, pharmacovigilance and access to medicines with particular focus on medicines for neglected diseases and other public health priorities and is an important initiative aimed at improving the regulatory environment and ensuring safe, effective and quality medicines.

CLINICAL TRIALS COMMUNITY (CTC) PLATFORM PARTNERSHIP

The clinical trial community is connected through an online platform making the process of identifying African clinical trials sites effortless by providing easy access to African clinical trialists, site feasibility data and regulatory and ethics information all on one platform. Promoting clinical trial sites, their capacity, capabilities, and site feasibility intelligence they provide an easy to navigate platform for key stakeholders. Increased collaborations will ultimately lead to improved sustainability of sites.

REGULATORY REQUIREMENTS CAN POSITIVELY INFLUENCE CLINICAL SUPPLY CHAIN OUTCOMES.

Regulatory agencies are not only limited to MoH's, DoH's, (Ethics Committee, etc) in each of the 54 countries. They also include Health, Customs, Standards, Revenue and Transport Authorities, amounting to over 160 regulators across the African Continent, and hence a deeper understanding of their processes, document requirements and most importantly 'Approval Time-Lines' which will influence clinical supply chain outcomes.

Current adoption of online submissions and standardisation is gaining traction and is already proving to be a game changer.

IMPORT CONTROL IN EAST AFRICA

East African countries manage import control through interconnected online platforms for health, customs, and revenue departments. Each department requires unique login credentials, passwords, and payment uploads from registered local entities.

For instance, in Kenya, only registered healthcare professionals can initiate the import/export process through the PPB portal. Likewise, only a freight clearing agent registered with the Kenya Revenue Authority (KRA) can finalise the online process.

Knowledge of up-to-date Value Added Tax and Import Duty regulations and obligations, together with the correct value of the consignment, must be met for each shipment to ensure time-scales are met.

This typically creates a bottleneck if we are not in full command of the processes. One issue arose when a -20'C consignment arrived and nobody knew where it was, which Freight company had delivered it, which location was the freezer in, couldn't access Customs Warehouse – the systems were Off-Line. The Sponsor's Export Division' sent it through without pre-notifications.

Fortunately, Oximio located it within the 11th hour and saved the day and pre-empted more stringent control mechanisms.

OVERCOMING LANGUAGE BARRIERS

There are many different languages spoken and understood across Africa. Thus documents, submissions, product labelling and so on must be clearly understood and accepted from country to country.

In one instance, a drug from a study in Lithuania was needed in Ghana. However, the labels needed to be translated. This was routed to our Kenya Customs Bonded depot and the labels were verified by Ghana FDA so that GMP relabelling could be performed, approved and despatched to sites in Ghana.

Technology – Trial Site Connectivity

One of the major challenges of conducting clinical trials in Africa is the lack of reliable and consistent internet connectivity, which can hinder communication between patients and researchers, as well as data collection and analysis.

The deployment of satellite-based internet technology, such as Starlink, has the potential to significantly improve clinical research in Africa, particularly from the patient's perspective. High-speed internet access to remote and under-served areas can help overcome this challenge and facilitate better patient engagement in clinical research. Patients can easily communicate with researchers, access study information and resources, and receive updates on the progress of the trial.

The deployment of satellite-based internet technology, such as Starlink, has the potential to significantly improve clinical research in Africa, particularly from the patient's perspective.

This can lead to improved patient retention and compliance, ultimately enhancing the quality and reliability of the trial results.

Telemedicine and virtual consultations can become more feasible, allowing patients to receive medical care and advice without having to travel long distances. Overall, the deployment of technologies such as Starlink in Africa has the potential to revolutionise clinical research and healthcare access for patients.

PATIENT CONNECTIVITY

Zero rating and reverse data billing are innovative solutions that can help patients stay connected during clinical trials, even in areas with limited or no internet connectivity. These solutions allow patients to access clinical trial information, communicate with researchers, and participate in virtual consultations without incurring data charges, ultimately improving patient engagement and retention in the trial.

Zero rating refers to the practice of exempting certain types of internet traffic from data charges. By zero rating clinical trial-related data, patients can access study information, communication tools, and virtual consultations without worrying about data costs, making it easier for them to stay connected and engaged throughout the trial.

Reverse data billing allows data charges incurred by patients during clinical trials to be billed directly to the trial sponsor rather than the patient. This removes the financial burden of data charges from the patient, making it easier for them to participate in the trial and stay connected throughout the study.

By implementing these innovative solutions, clinical trial sponsors can help overcome some of the major barriers to patient engagement and retention, particularly in low- and middle-income countries where data costs can be a significant burden. Patients can stay connected with the research team, receive study updates, and participate in virtual consultations without incurring additional costs, ultimately improving the quality and reliability of the trial results and advancing medical knowledge.

How Regulatory Requirement Differences Can Affect Shipping & Distribution

Covid-19 was certainly a stress test for change for all of us.

Lack of supply chain visibility was exacerbated by the fact that knowledge of the supply chains in the African continent was not deep enough.

Increasing Multi-Site, Multi-Country studies will have fundamental differences in regulatory requirements from country to country which can affect the supply chain if the shipper/research company is not acutely aware of each country's regulations.

This can result in customs clearance delays, temperature excursions and loss of clinical trial continuity.

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TAKING A PRO-ACTIVE APPROACH TO REGULATORY CHANGES

More Multiple Country, Multiple Trials are being conducted in Africa because we have a disease burden similar to the rest of the world. Non-communicable diseases such as hypertension, cardiovascular disease, chronic respiratory diseases, diabetes and cancers are considered high and presents opportunities to the research companies.

We need to take a proactive approach and prepare for changing regulatory landscapes by understanding and adopting more advanced supply chain risk management practices by ensuring compliance with future regulations by keeping up-to-date with supply chain changes and expectations with visibility and continuous risk monitoring.

We need to understand each country's Customs processes as this is directly related to imported clinical products as too is the description of clinical material, ambiguous meanings, HS Code misclassifications, PVoC (Pre-Verification of Conformity) to name a few.

EXAMPLE: HS CODES

Simply put – The Harmonization Code can differ by ONE digit and get stopped by Customs. Lab Kits are typically susceptible to intense scrutiny, as too are Medical Devices made up of multiple components.

EXAMPLE: PVOC INSPECTIONS

CoC's are typically only accepted for medicines – all allied product, (ancillaries, devices, etc.) need to be inspected in the country of origin, by a recognised entity who have been approved in country of import.

Collaboration – The Key to Success

Strong believers that collaboration is the key to success, Oximio funded the launch of the Clinical Research Society of Kenya, a non-profit organisation set-up to serve as a leader and conduit within the clinical trials community.

The Society believes that by leveraging their collective experience they can influence the quality of clinical research sites and stakeholders to help drive growth of clinical trials in the region.

By working together and fostering relationships and conversations across all agencies within the regulatory landscape in Africa, it is hoped that clinical trial approval timelines can be expedited. Third-party coalitions and collaborations with experts who have

Clinical Research Society of Kenya - Leveraging collective experience to influence quality & drive the growth of clinical trials..

CLINICAL RESEARCH SOCIETY OF KENYA

developed excellent relationships with sponsors, CROs, regulators and freight carriers help maintain an up-to-date supply chain risk management process.

This means that we can adapt quickly to any regulatory changes and make timely and effective decisions to improve supply chain outcomes.

This is further enhanced via the deployment of easy-to-access technology, maintaining sponsor, CRO, site and patient connectivity.

IN2AFRICA AND DE-RISKING CLINICAL TRIALS

Attracting more clinical trials within the continent depends on an effective and robust supply chain. Oximio's new, African initiative, "IN2Africa" sets out to de-risk the process and is already operational in selected African countries.

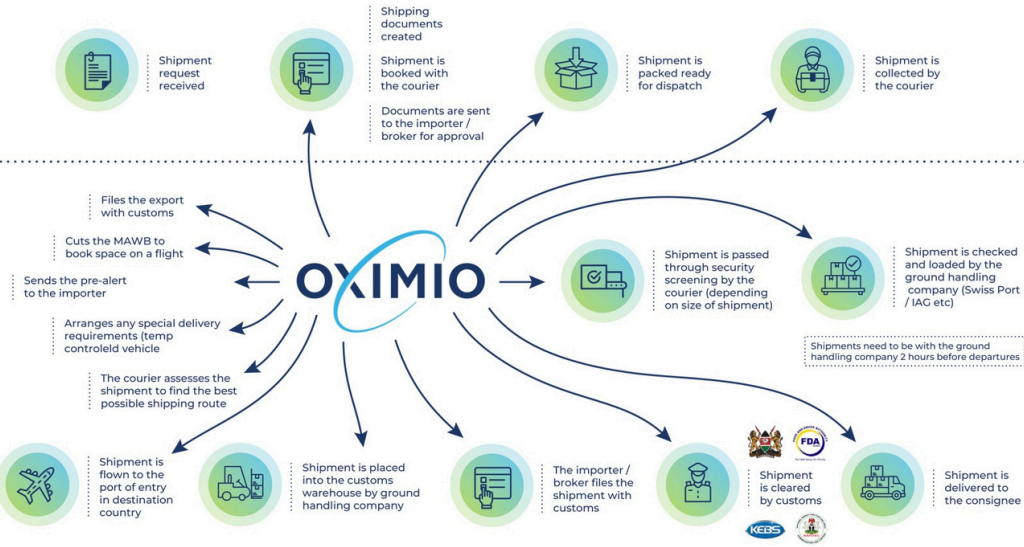
By partnering with proven industry experts across sub-Saharan Africa, IN2Africa provides a one-stop-shop

principle across the entire continent, reducing supply chain risks and benefiting from the services and advantages of a customs bonded warehouse.

Moving on from a traditionally fragmented, clinical supply chain across multiple countries, Oximio's IN2Africa supply chain strategy provides a reshaped infrastructure acting as a central point for the co-ordination of customs, regulatory and logistics handling.

A game-changing concept, we believe it will go a long way to provide robust supply chain solutions, build trust and attract more clinical trials IN2Africa.

By doing so, it will address the disease burden issues and create more opportunities for clinical research companies throughout sub-Saharan Africa.



WORK WITH OXIMIO IN SUB-SAHARAN AFRICA

Founded in 2004, Oximio's Kenyan and South African operations were established in 2021, expanding operations and service coverage across the complete African landscape. Our centralised customs bonded distribution facility in Africa, with state-of-the-art storage and distribution, is essential in maintaining the clinical supply chain across all African states. This provides centralised procurement to rapidly move clinical trial material, manage biospecimen transportation via our CryoSure® dry ice shipping solution, perform re-labelling, contributing positively to clinical supply chain outcomes.

In September 2023, Oximio, South Africa, secured a resolution to the SAHPRA (South African Health Products Regulatory Authority) licence for the handling of medical cannabis. This places Oximio, South Africa, as a premier distributor for medical cannabis products for commercial or clinical trial purposes from Africa, extending the company's reach to support the international market.

GLOBAL SUPPLY CHAIN SOLUTIONS FOR CLINICAL TRIALS

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